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(71) Applicant (for all designated States except US): **RHINOMETRICS A/S [DK/DK]**; Strandvejen 58, DK-2900 Hellerup (DK).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **RASMUSSEN, Steen, B. [DK/DK]**; c/o Rhinometrics A/S, Strandvejen 58, DK-2900 Hellerup (DK). **FOGED, Peter [DK/DK]**; c/o Rhinometrics A/S, Strandvejen 58, DK-2900 Hellerup (DK).

(74) Agent: **ZACCO DENMARK A/S**; Hans Bekkevolds Allé 7, DK-2900 Hellerup (DK).

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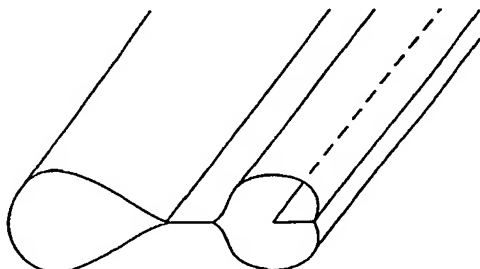
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(54) Title: **DEVICE FOR MEASURING IN BODY CAVITIES**



(57) Abstract: The inflatable catheter has a proximal end and a closed distal end for inserting into a human or animal body cavity. The catheter has at least a longitudinal, inflatable section that is flexible and essentially non-stretchable and which collapses when not inflated. Preferably, the inflatable section comprises a web of material with opposing edges secured to each other, e.g. by welding.

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Device for measuring in body cavities**BACKGROUND OF THE INVENTION**

- 5 The present invention relates to the examination and measurement of constrictions or passages in cavities by means of acoustic reflectometry using a device comprising an electric signal source, a catheter to be introduced through an entrance to a cavity, a first transducer for transfer of an activation signal from the signal source to and through the catheter, a second trans-
- 10 ducer for reception of response signals from the catheter, the first and second transducers being connected with the, and a computer adapted for analysis of the response signals in relation to the activation signal.

- Various methods are known for the examination and measurement of occlu-
- 15 sions, deformations, movements etc. in various human and animal cavities, e.g. airways such as the pharynx and the larynx, the gastro-intestinal tract, the urinary system, blood vessels etc.

- US 5 823 965 discloses an apparatus and method for examining human or
- 20 animal body cavities such as airways and the gastro-intestinal tract. The device has a flexible hose-like catheter, which is introduced into the cavity with the distal end of the catheter beyond the zone to be examined. An acoustical excitation signal is sent into the interior of the catheter. Irregularities reflect the acoustical signal, which is picked up by a receiving transducer and ana-
- 25 lysed. Such method is often referred to as reflectometric examination. A computer displays results of the examination on a screen. The device may comprise means for establishing a positive static pressure with the purpose of dilating the flexible wall of the measuring zone.

- 30 The purpose of the invention is to provide improvement in the measuring accuracy in such devices.

SUMMARY OF THE INVENTION

5 This purpose is achieved by means of a device and a catheter according to the invention. The inflatable catheter has at least a longitudinal, inflatable section that is flexible and essentially non-stretchable and which collapses when not inflated. Preferably, the inflatable section comprises a web of material with opposing edges secured to each other, e.g. by welding.

10 When inflated the flexible and essentially non-stretchable catheter with the proper circumferential dimensions may adapt more closely to the sidewall of the body cavity without deforming this and hence provide more accurate information on the anatomy and physiology of the body cavity it self without introducing unnecessary disturbances to delicate tissue and structures.

15 In a preferred embodiment the catheter has an inflatable section that comprises a web of material with opposing edges secured to each other, e.g. by welding or by means of adhesive. Such a catheter can be manufactured with two or more lumens separated by welding seams and can be manufactured
20 in any desired length and with any desired length of its circumference including variations of the circumference in the longitudinal direction. Thus, catheters can be manufactured to be suitable for use in examinations of almost any conceivable natural and pathological structure.

25 The catheter may be manufactured from materials such as LDPE, HDPE, PET, polyurethane, polyetan and other materials with similar mechanical properties or from combinations of such materials. The catheter is then manufactured with a material thickness between 10 and 100 μm , preferably between 10 and 50 μm .

30

In preferred embodiments of the method, the cavity is an organic cavity, e.g. the respiratory passages, the blood or lymph tracts, the alimentary canal, or the urinary system or sections thereof of an animal or a human body. The invention also offers the possibility of making prostate or uterus examinations and similar examinations in body cavities like the urinary passage etc.

Other features and advantages of the present invention will become apparent from the following description of embodiments of the invention, which refers to the accompanying drawings.

10

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a block diagram of the basic lay-out of the device according to the an embodiment of invention;

15

Figure 2 is a perspective drawing of part of the catheter, at the location where the measurement is made;

20

Figure 3 is a perspective drawing of part of the catheter in another embodiment of the invention;

Figure 4 is a sectional view of the catheter according to FIG. 3 in a sectional plane at right angles to the axis of the catheter;

25

Figure 5 illustrates the placing of a catheter in the upper airways of a patient being examined for tongue-fallback;

Figure 6 illustrates the placing of a catheter in the upper airways of a patient being examined for stertorous respiration; and

30

Figures 7 - 12 illustrate preferred embodiments of the catheter of the invention.

DETAILED DESCRIPTION OF THE INVENTION

5

Figure 1 shows the basic layout of the device according to the invention. A catheter 1 has a proximal end A and a distal end B. The catheter 1 is for inserting, with its distal B end fist, through a natural or surgically prepared opening in a human or animal body. At its proximal end A, the catheter 1 is
10 connected to auxiliary equipment, which is known per se and not illustrated, used for inserting the catheter in, e.g., the airways of a patient, through the mouth or the nostrils, or in the urinary system or an artery. After insertion the distal end B of the catheter will be in the cavity of the patient.

15 A controller 2 includes a signal generator that is adapted to give an activation signal to a transducer 3 connected to the catheter 1. The signal generator delivers the same signal to a signal analysis processor 4. An electro-acoustic transducer 5 is connected to the catheter 1. When an excitation signal is transferred from the signal generator 2, the transducer 3 emits an acoustic
20 signal that will propagate into the catheter. At the distal end of the catheter and at irregularities in the cross-section response signals are reflected and received by the transducer 5 and from there led to the signal analysis processor 4.

25 The system comprises a fluid pump 40 that is controlled by the controller 2 and connected to the proximal end A of the catheter through a tube 41. In the preferred embodiment the fluid is air. The pump 40 is capable of increasing the pressure in the catheter in a controlled manner, e.g. continuously or step-wise in small increments. A pressure and flow control unit 42 comprises a
30 pressure transducer for monitoring the pressure in the catheter 1, and a pressure release valve that opens at a predefined pressure and releases the

pressure in the catheter to prevent overpressure. The pressure and flow control unit 42 may also comprise a flow control unit that detects and prevents an excessive flow of fluid in case of e.g. a ruptured catheter. Static and low-frequency pressure data from the pressure transducer is transmitted to the signal analysis processor 4 for processing and/or for display. In this context the term "low frequency" is intended to cover frequencies of physical movements that occur in human and animal physiological processes of normal and pathological nature. Thus, the pressure transducer preferably has an upper frequency limit of at least 10 - 100 Hz depending on the nature of the processes to be examined.

The signal analysis processor 4 is connected to a computer 6 with a screen 7 by means of which it is possible to present an image, which e.g. graphically illustrates the results of the examination and measurements made.

The electro-acoustic transducer 3 can be of any suitable type known per se, e.g. an electromagnetic transducer, an electrostatic transducer, a piezoelectric transducer, etc. Its task is to transform the electronic signal from the signal generator 2 into an excitation signal in the interior of the catheter 1.

The electro-acoustic transducer 5 can also be of the above mentioned type, e.g. a microphone, the purpose of which is to receive an acoustic response signal from the distal end of the catheter and to transform this response signal into an electric signal which is led to the signal analysis processor 4.

The electro-acoustic transducers 3 and 5 in figure 1 are preferably piezoelectric transducers or other reciprocal transducers, which in response to an electrical input signal emit an acoustic output signal, and in response to an acoustic input signal emit an electrical output signal. Instead of separate transmitting and receiving transducers 3 and 5 a single transducer can be used both as transmitter and receiver.

The analysis itself of the response signal in relation to the excitation signal belongs to a technique known per se.

- 5 A transducer 20 has been introduced from the outside through the outer chamber 12 and through the wall 15 so that the response signal receiving end 21 of the transducer 20 is located in the lumen 11.

Figure 5 illustrates the use of the catheter in order to determine the position
10 of and measure the so-called tongue fallback of a patient, e.g. the situation where the patient's tongue narrows the upper airways.

Here the catheter has been introduced through the nostrils and into the air passage. Part of the catheter is compressed by the rear end of the tongue in
15 the zone D.

Figure 6 shows the situation illustrated in figure 5 as well as the situation where said soft parts of the palate compress the catheter in the zone E.

20 Figure 6 illustrates the situation where a patient is to be examined for vibrations in the soft parts of the palate, e.g. typically stertorous respiration. The vibrations in the zone E will influence at least one of the outer chambers of the catheter and the measurement equipment can carry out the positioning and measurement.

25 Anatomical, physiological, surgical or other medical considerations may influence the choice of the inner and outer dimensions of the catheter and its length, and the catheter may therefore be manufactured in different diameters and lengths.

30

Exact examinations of persons, whose airways are blocked during their sleep and who can be described as having stertorous respiration, are naturally very difficult and through the ages many failed corrective operations have been made on these patients.

5

This is the reason why equipment which acoustically registers the stertorous respiration does not activate an alarm with sufficient security, as the non-occurrence of a "snoring sound" is either due to a quiet, steady respiration with a low regular flow, which is all right, or the airways being blocked for a

10

An internal measurement has the advantage that the patient is not awakened during the measurements by the excitation signal and at the same time the measurements are not influenced to a large extent by the high tone sound spectrum of the snoring sounds.

15

The measurement probe itself is very easy to introduce ambulatory into the patient's nose before the night, in cooperation with a doctor or a nurse.

20 A correct "tightening" through the nose happens automatically due to the reflectory swallowing, and a connection (transducer/microphone part) at the end which projects out of the nose can be made without problems.

It should also be noted that the measurement equipment (hardware/software) which adequately makes the measurements in each chamber and during the measurements changes the static pressure in each chamber can also concurrently give information about the elasticity of the tissue giving counter-pressure to the surface of the chambers.

25

30 By establishing a static pressure in the catheter and superimposing acoustic signals with frequencies ranging from infrasound up to e.g. 200 Hz in the lu-

men and the chambers, and combining this low-frequency sound signal with the acoustic reflectometric measurements, such as described in US 5 823 965, it is possible also to obtain valuable information about the elasticity in the walls to which the catheter wall establishes a contact during the various pressure conditions.

Catheters suitable for use with the invention can be manufactured using traditional methods such as extrusion or moulding using a mandrel.

10 Figures 7 - 11 illustrate preferred embodiments of the catheter suitable for use with the invention.

In figure 7 a strip or web of a weldable sheet material has been folded onto it self and welded along the overlapping edges to form a single-lumen catheter.

15

In figure 8 the catheter in figure 7 has been "inverted" by turning the inside out so that the welding seam is inside the lumen of the catheter. Alternatively, the overlapping edges may be welded in the shown position with the welding seam inside the lumen of the catheter. This embodiment gives less discomfort to the patient when inserting and removing the catheter than the catheter in figure 7.

20

Figure 9 shows an embodiment of the catheter in figure 7 with two parallel welding seams providing a two-lumen catheter. Catheters with three or more lumens may also be manufactured in this way.

25

Figure 10 shows another two-lumen catheter produced from the catheter in figure 8 by adding a second welding seam like in figure 9.

30 Figure 11 shows an embodiment where the welding seam of the overlapping edges of the sheet material does not protrude from the catheter or into the

lumen of the catheter. Like in figures 9 and 10 this catheter can be divided into two or more lumens by longitudinal welding seams.

5 The distal end portion of the catheter of the invention can have a structure that makes it suitable for inserting through a natural or surgically prepared opening in the human or animal body. As illustrated in figure 12, the proximal end portion of the catheter can have a structure, e.g. a tubular member that makes it suitable for connecting to external equipment such as illustrated in figure 1. The materials and the structure of the catheters of the invention are
10 chosen to cause the minimum possible disturbance to the surrounding tissue and anatomical structure of the human or animal body, and in particular to the structure to be examined. This is obtained by choosing the materials and structure so that at least the inflatable portion collapses when not inflated.

15 As an alternative to welding, the overlapping edges may be secured to each other by means of adhesive or other suitable means.

Catheters as shown in figures 7 - 11 can be manufactured in any desired length and with any desired length of its circumference including variations of
20 the circumference in the longitudinal direction.

CLAIMS:

1. An inflatable catheter (1) with a proximal end (A) and a closed distal end (B) for inserting into a human or animal body cavity, the catheter having at least a longitudinal, inflatable section that is flexible and essentially non-stretchable and which collapses when not inflated.
2. A catheter according to claim 1 wherein the inflatable section comprises a material chosen among LDPE, HDPE, PET, polyetan, polyurethane and other materials with similar mechanical properties.
3. A catheter according to claim 1, where the inflatable section comprises a material having a thickness between 10 and 100 μm , preferably between 10 and 50 μm .
4. A catheter according to any one of claims 1 - 3, wherein the inflatable section comprises a web of material with opposing edges secured to each other.
5. A catheter according to claim 4, wherein the web is of a weldable material, and the opposing edges are secured to each other by welding.
6. A catheter according to claim 5 having two or more lumens separated by welding seams.
7. A catheter according to any one of claims 1 - 6 comprising a tubular member at the proximal end (A).
8. A device for measuring in human or animal body cavities, the device comprising catheter (1) with a proximal end (A) and a closed distal end (B) for inserting into the body cavity, a fluid pump for inflating the catheter and

adapted to provide a fluid pressure to the catheter so as to inflate the catheter, wherein the catheter is in accordance with any one of claims 1 - 7.

9. A device according to claim 7, where the fluid pump is controllable to vary
5 the fluid pressure supplied to the catheter.

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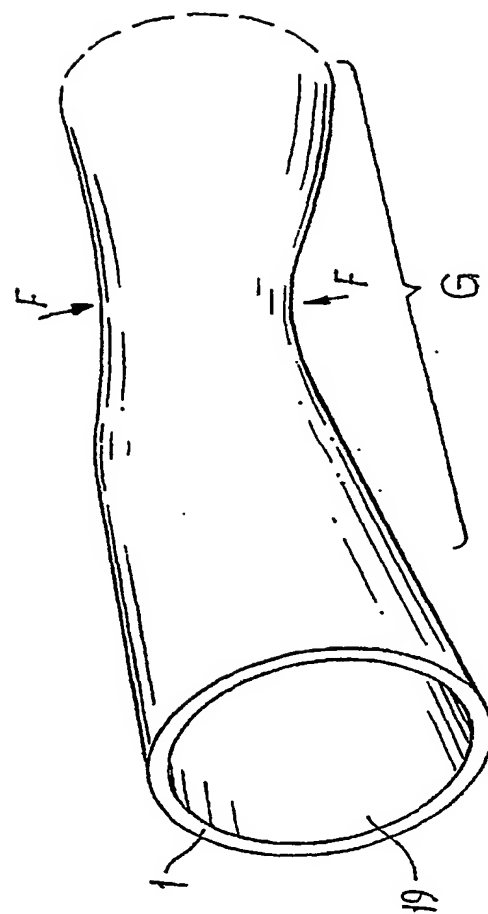
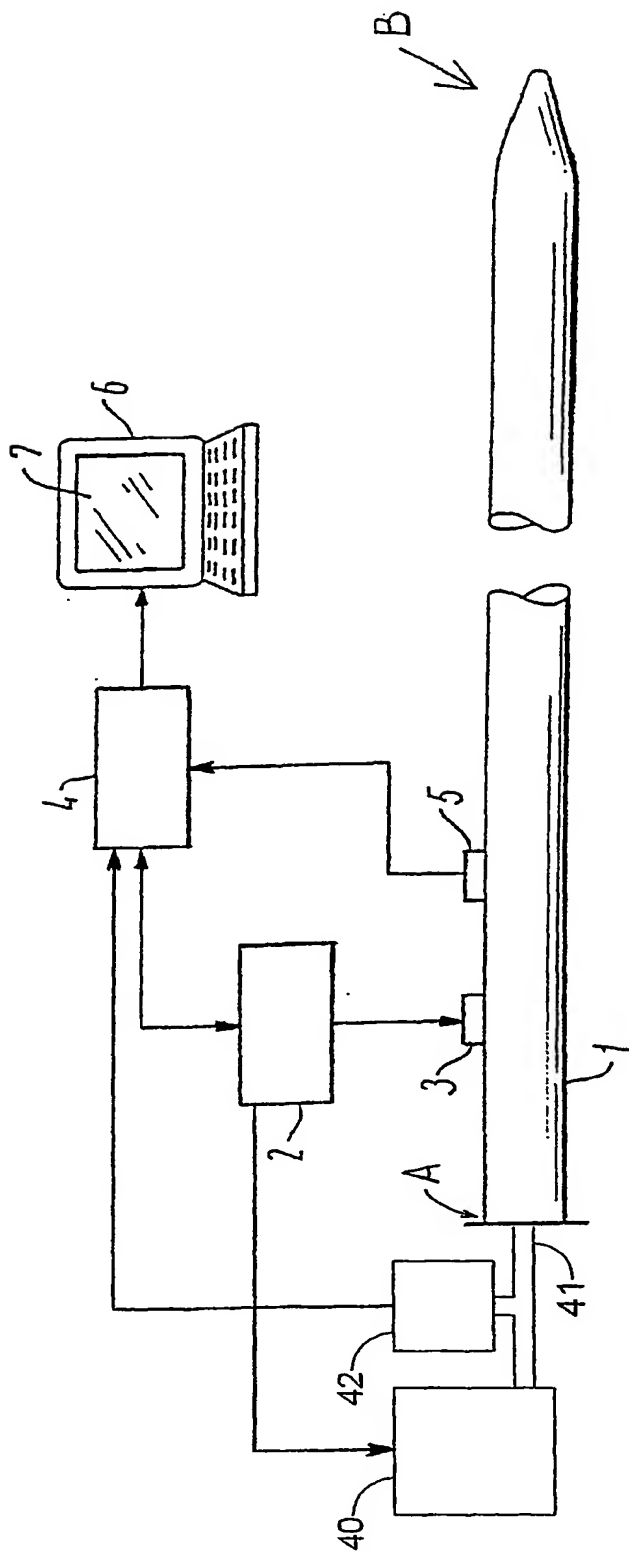


FIG. 1

FIG. 2

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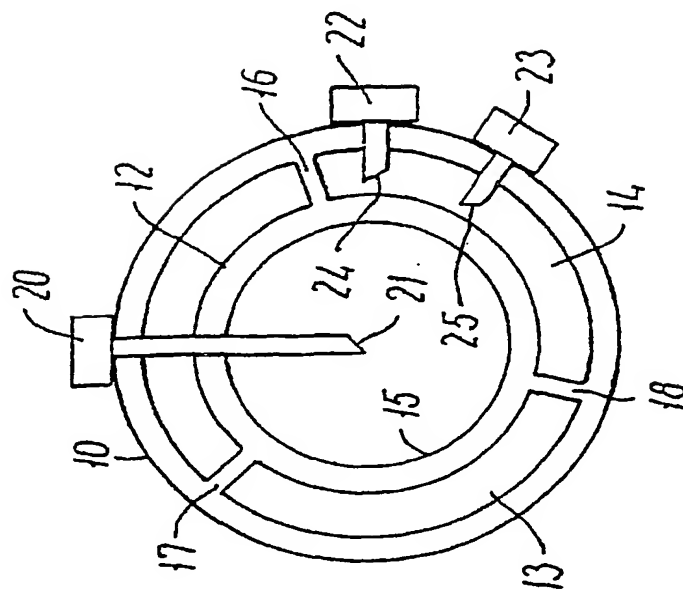


FIG. 4

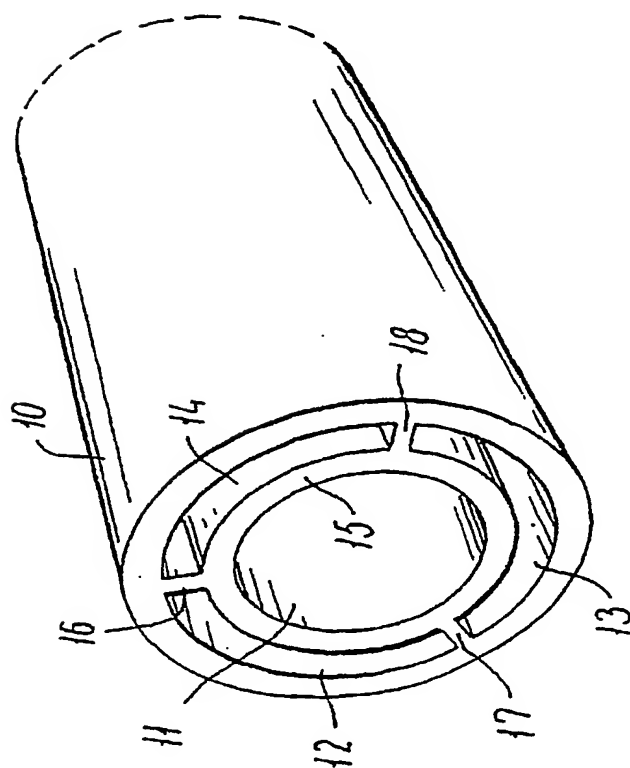


FIG. 3

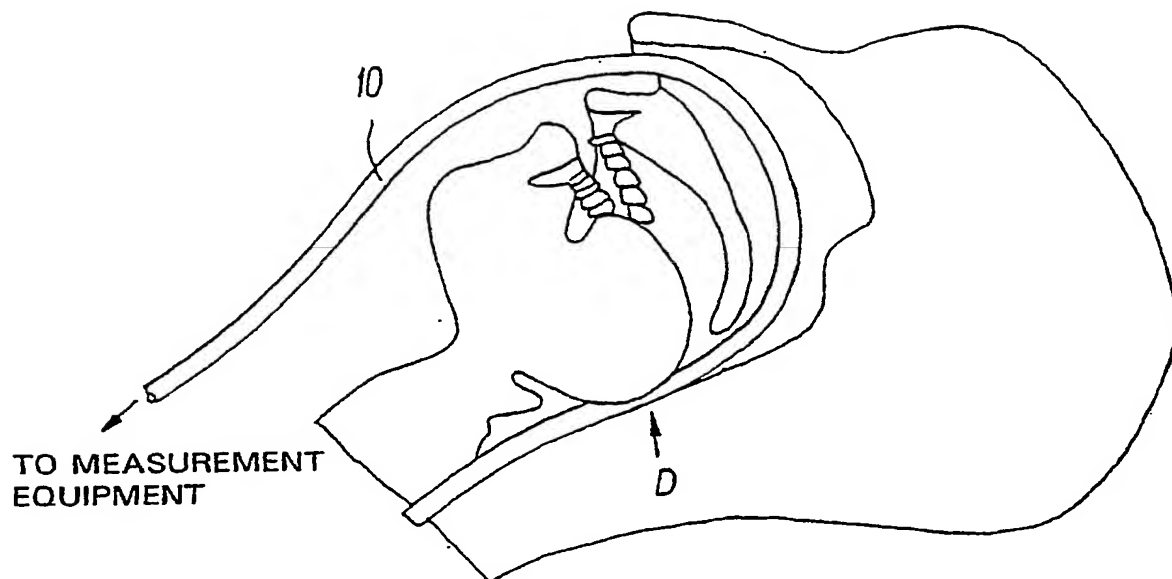


FIG. 5

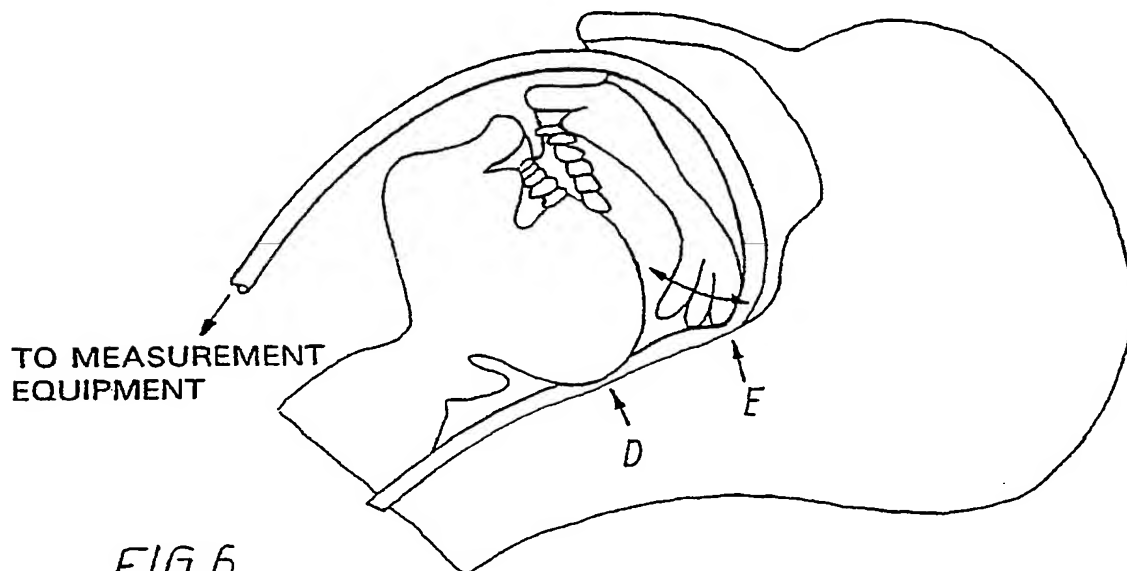


FIG. 6

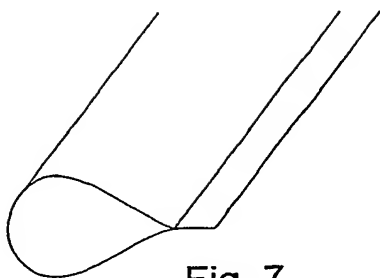


Fig. 7

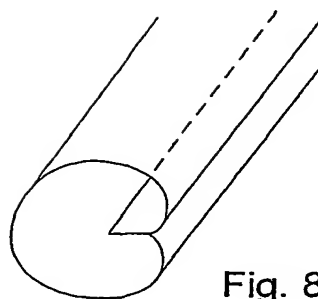


Fig. 8

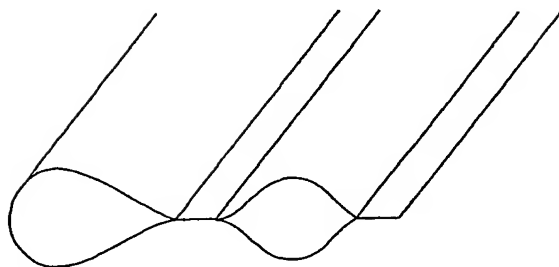


Fig. 9

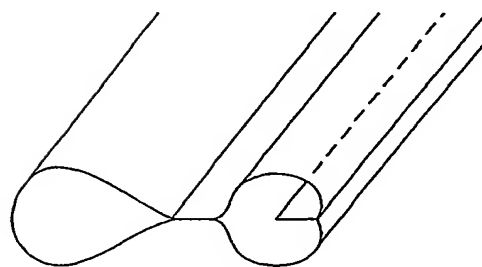


Fig. 10

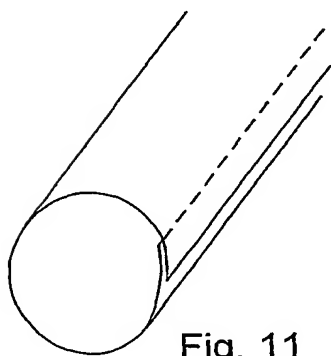


Fig. 11

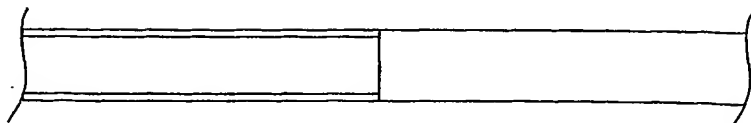


Fig. 12